

Medtronic

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November 19, 2021

U.S. Environmental Protection Agency
Office of Air Quality Planning and Standards
U.S. EPA Mailroom (C404-02)
Attn: Ms. Tiffany Purifoy, Document Control Officer (ESD #322)
109 T.W. Alexander Drive
Research Triangle Park, NC 27711

RE: Ethylene Oxide Commercial Sterilization Section 114 Survey Response by Medtronic

Dear Ms. Purifoy:

Please find enclosed Medtronic's responses to the United States Environmental Protection Agency's Ethylene Oxide Commercial Sterilization Supplemental Section 114 Survey from September 2021 (the "Supplemental Survey").

The Supplemental Survey requested certain information on the following Medtronic-affiliated facilities:

- Covidien, 195 McDermont Road, North Haven, Connecticut
- MPROC – Villalba, State Road, 149 KM 56.3, Villalba, Puerto Rico
- HeartWare, 14440 Northwest 60th Avenue, Miami Lakes, Florida
- Xomed Surgical Products, 6743 Southpoint Drive North, Jacksonville, Florida
- Medtronic – Rice Creek, 7000 Central Avenue Northeast, Fridley, Minnesota
- Medtronic PRL, 115 Yellow Pine Street Northwest, Coon Rapids, Minnesota
- MPROC – Juncos, Road 31, KM 24.4, Ceiba Norte Industrial Park, Juncos, Puerto Rico

As requested by the EPA and in accordance with Section 114 of the Clean Air Act, 42 U.S.C. § 7414, Medtronic has made all reasonable efforts within the time provided by the EPA to collect and organize the information and records requested by the Supplemental Survey. Per previous correspondence with EPA, Medtronic did not create any new documents to respond to this Supplemental Request.

Medtronic has collected and organized all readily available information for an electronic file transfer (non-CBI submission) or an enclosed flash drive (CBI submission), which contain Microsoft Excel workbooks and accompanying Attachments. The password for the encrypted flash drive is: **MDT*114Response.**

Medtronic hereby submits the enclosed responses to the Supplemental Survey in accordance with its obligations under the Clean Air Act. Although Medtronic has endeavored to provide detailed responses based on all readily available information, Medtronic objects to the requests for information in Miscellaneous, Table 2 (Requests L-8 through L-11) to the extent those requests exceed the authority granted to the EPA under the Clean Air Act and such requests are overly broad and unduly burdensome given the various factors that contribute to management of products along Medtronic's supply chain. Medtronic has numerous factors which may impact its supply chain and distribution of its products, including space constraints and ultimate disposition of products. Depending upon the specific loads, shipments vary on a regular basis. Subject to and without waiver of these objections, Medtronic is providing generalized responses for each site for the "usual" supply chain routes with respect to the Requests L-8 through L-11, to the extent available. Furthermore, Medtronic submits its responses to the Supplemental Survey without waiving any rights or objections and reserves its right to supplement or amend its responses, as appropriate.

Confidential Business Information

In accordance with 5 U.S.C § 552(b)(4), 40 CFR Part 2, Subpart B, and other applicable authority, Medtronic hereby requests that certain information included in the enclosed Microsoft Excel workbooks and accompanying Attachments be protected from public disclosure as confidential business information ("CBI"). As instructed by the EPA, fields in the enclosed Microsoft Excel workbooks containing CBI have been shaded in red. In addition, all Attachments containing CBI include the language "CBI" in the applicable file name and have also been clearly marked "CONFIDENTIAL BUSINESS INFORMATION – DO NOT DISCLOSE."

The CBI provided by Medtronic in response to the Supplemental Survey includes cost information (or information that could be used, directly or indirectly, to derive costs), personally identified information, facility design, layout and process information, and proprietary policies and procedures. All records and information designated as CBI in the enclosed responses is maintained and protected by Medtronic as CBI, the public disclosure of which would result in substantial commercial harm to Medtronic. In addition, public disclosure of such information could threaten the security of Medtronic's operations.

If EPA intends to consider making publicly available any of the information that Medtronic has designated as CBI, Medtronic respectfully requests the opportunity to address EPA's questions or concerns prior to any final agency confidentially determination or public disclosure.

Certification

In the Supplemental Survey, EPA has provided fields for separate certifications by four individuals: a reporter, facility representative, professional engineer, and certified industrial hygienist. EPA has not provided an explanation or basis as to why it has provided fields for separate certifications for a single response to the Supplemental Survey. Based on a telephone conversation between Medtronic's counsel and EPA on October 5, 2021, EPA confirmed that not all certification fields are required, but at least one certification is required for completion of each Microsoft Excel workbook.

Medtronic has provided at least one certification for each Microsoft Excel workbook. Each certifier certifies that based on a review of the responses to the Supplemental Survey, readily available records and information, and discussions with facility personnel, the responses are true, accurate, and complete to the best of their knowledge and belief at this time. Further, as requested by EPA, Medtronic has identified Mr. Robert Kreye as the person who is available to answer any follow-up questions about the information provided in response to the Supplemental Survey. Mr. Kreye can be contacted at robert.e.kreye@medtronic.com or 763-526-1225.

Please contact Patricia Duft at patricia.h.duft@medtronic.com or Geoff Rathgeber at geoff.c.rathgeber@medtronic.com if you have any other questions regarding the enclosed response to EPA's Supplemental Survey.

Sincerely,

A handwritten signature in black ink, appearing to read "Patricia Duft", written over a horizontal line.

Pat Duft
Medtronic

cc: Robert Kreye
Geoff Rathgeber